

REMARKS

Support for the amendment to the claims may be found in Applicants' specification as originally filed at pages 8-14; specifically, page 8, lines 23-28, page 10, lines 11-16, page 12, lines 5-10, page 12 lines 5-17, page 13, lines 9-29, and page 14, lines 1-5 and 15-18. No new matter has therefore been introduced.

In the 06/05/2008 Office Action, the Examiner has finally rejected claims **35-40** pending in the application. After entry of the foregoing amendments, claims **35-40** remain pending in the application. Reconsideration of the previously pending and currently amended claims is respectfully requested.

PRIORITY – 37 C.F.R. § 1.78 (a)(3)

Applicant acknowledges and thanks the Examiner for the indication that the petition to claim priority pursuant to 37 C.F.R. § 1.78(a) (3) is waiting for a decision and that the Applicant will be notified in due course.

INVENTORSHIP

The Office Action indicates that it has been found that “[i]n view of the papers filed April 29, 2008, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by adding the following three inventors: James H. Brown, Sambasivarao Koritala, and Robert Kleiman. The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.” Applicant acknowledges and thanks the Examiner for this correction of inventorship.

ELECTION/RESTRICTIONS

The Office Action indicates that “[t]his application contains claims 23-34 drawn to an invention nonelected with traverse in the reply filed on 07/16/2007. A complete reply to the final rejection

must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.” In response, the Applicant has canceled claims 23-34 in accordance with the Examiner’s requirement.

Further, the Office Action indicates that the previous “rejection of claims 35-40 under 35 U.S.C. §112, second paragraph, as being indefinite” is “overcome by virtue of applicants’ amendments and remarks.” Applicant acknowledges and thanks the Examiner for this indication.

35 USC § 102(e)

Claims **35-40** stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,649,177 to Howard *et al.* (“the Howard reference”). The Office Action maintains its previous rejection, asserting that “US ‘177 disclosed hydrolyzed jojoba oil added to cosmetic compositions to enhance their desirable properties and used to good effect in [] varieties of cosmetic formulations (abstract; col.2, lines 52-58).” Further, the Office Action asserts that the Howard reference teaches “that the jojoba oil is added to the cosmetic formulation during preparation (col. 2, lines 65-67), which reads on the step of the claimed method.” Additionally, the Office Action asserts that “[e]xample 4, tables 2, 7, 8, and 12 of the reference disclosed topical cosmetic formulation comprising jojoba protein and wheat germ oil, which meets the limitations of materials claimed by claims 36 and 39. The reference disclosed hydrolyzing the jojoba oil by alkali (example 1).” The Office Action then recites the first and second paragraph of page 14 of Applicant’s application as filed to conclude:

“[t]herefore, the reference disclosed the same method as applicant’s method of obtaining the claimed composition that comprises polar hydrophilic salts and non-polar unsaponifiable materials. Hence, since the reference disclosed hydrolyzed jojoba oil produced by the same method as applicant’s method, then the composition produced by the reference will inherently have the same hydrolysis product. Jojoba oil inherently has the same amount of unsaponifiable materials prior to hydrolysis. The neutralization of acidic gelling agent is inherent.”

Finally, the Office Action states that

“U.S. '177 disclosed adding the jojoba oil product to cosmetic composition including gels (col. 3, lines 4-20). The reference disclosed gel comprising carbomer (col. 16, line 38 till col. 17, line 18). Applicant disclosed carbomer as one of the acidic gelling agent in page 15, last paragraph.”

In conclusion, the Office Action states that “[t]he limitations of claims 35-40 are met by US ‘177.”

Applicant respectfully traverses this rejection and submits that the rejection is substantively defective.

For a reference to be anticipating, each and every element of the applicant’s claimed subject matter must be contained in the cited reference. MPEP § 2131. Omission of any claimed element or limitation, no matter how insubstantial, is grounds for traversing a rejection based on 35 U.S.C. § 102.

In this case, the Howard reference fails to teach or disclose a “method of providing a composition for topical application, wherein said composition increases substantivity and neutralizes an acid gelling agent; said method comprising the step of neutralizing the gelling agent with an effective amount of said composition; and wherein said composition comprises polar hydrophilic salts and non-polar unsaponifiables, wherein said polar hydrophilic salts and said non-polar unsaponifiables comprise the products of hydrolysis of a lipid comprising jojoba oil, wherein said lipid comprises at least more than about 10 weight percent long carbon chain material prior to hydrolysis”, as required by claims 35 and 38 as amended.

For example, the Howard reference fails to disclose the hydrolysis products of a lipid comprising jojoba oil, as required by claims 35 and 38 as amended. By contrast, the Howard reference teaches the hydrolyzed jojoba protein as a result of the *hydrolysis of de-fatted jojoba meal*. In other words, the Howard reference teaches removal of lipids, including jojoba oil, prior to hydrolysis. Specifically, the Howard reference states in Example 1 that “[t]his example describes a preferred procedure for the preparation of hydrolyzed jojoba *protein*, using *solvent extracted defatted jojoba meal as a starting material*. The meal is obtained from jojoba which has been conventionally press-treated with subsequent *solvent extraction to remove the jojoba*

oil, leaving the *defatted* meal.” (Emphasis added) See Howard col. 3, lines 45-50. Thus, the Howard reference explicitly discloses the removal of jojoba oil from the starting material, leaving only the defatted meal as the starting material for the hydrolysis of jojoba protein. While Howard states that trace amounts of residual oil, around 1.7%, remain, these small amounts are not within the scope of the claims, which requires the hydrolysis products to be *of a lipid*.

Additionally, Example 2 uses this same “jojoba meal” that was characterized in Example 1 as the starting material in which “a jojoba amino acid product is produced by acid hydrolysis of jojoba meal.” See Howard col. 5, lines 54-55. Example 3 also clearly uses a starting material of only jojoba protein in that “quaternized derivatives of hydrolyzed jojoba protein or jojoba amino acids are prepared. In the first step, 100 parts of the jojoba product (*either hydrolyzed jojoba protein or jojoba amino acid*) are added to a reaction tank.” See Howard col. 6, lines 18-23. Again, the “hydrolyzed jojoba protein” was produced in Example 1 from the defatted meal that has had the jojoba oil removed (the removal of jojoba oil is also inherent in the term “defatted meal”). Further, Example 4 clearly states that “[t]he following products were produced using the hydrolyzed jojoba protein products.... described in Example 1.” See Howard col. 6, lines 61-62. This is inapposite to the hydrolysis products of a lipid comprising jojoba oil, as required by claims 35 and 38 as amended.

By contrast, the Examiner asserts that “the present claims recited hydrolyzed jojoba proteins by reciting “organic material comprising jojoba oil, wherein said original organic material comprises at least more than about 10 weight percent long chain carbon material prior to hydrolysis.” Therefore the recited organic material, i.e., jojoba oil, is hydrolyzed.” Not only does the Examiner conflate the starting material (defatted jojoba meal) and the resulting materials (hydrolyzed jojoba protein) of the Howard reference, the Examiner actually equates the claimed starting material (lipid) to the jojoba protein of Howard.

Upon further dissection of the Examiner’s argument, it appears that the Examiner argues the following: hydrolyzed protein means organic material comprising jojoba oil – therefore jojoba

oil is hydrolyzed. This is, of course, not only preposterous but chemically impossible. A protein is not a lipid.

The Examiner, as well as anyone of ordinary skill in the art, would appreciate that lipids and proteins have mutually exclusive functions and properties. For example, lipids include fatty acids comprising a carboxylic acid groups (COOH) with long-chain hydrocarbon side groups (CH groups) that are connected together by single covalent bonds (saturated) or double covalent bonds (unsaturated). (See Exhibit A, pp. 278-279). By contrast, proteins comprise amino acids joined together as polymers to form proteins via peptide bonds. (See Exhibit B, p. 57). Amino acids contain “ α -amino groups” composed of nitrogen (N) and hydrogen (H) atoms and “ α -carboxylic acid groups” composed of carbon (C) and oxygen atoms (O). (See Exhibit A, pp. 56-57). These α -amino groups and α -carboxylic acid groups combine in a condensation reaction to release a water molecule, forming a resulting CO-NH linkage called a peptide bond. (See Exhibit B, p. 57). Similarly, hydrolysis such as by acid or enzyme treatment (See Howard col. 4, lines 25-32) of a protein results in breaking the peptide bond to produce individual amino acids.

Thus, it is clear that neither the starting material of Howard (solvent extracted defatted jojoba meal) or the resulting material (hydrolyzed jojoba protein) is analogous to the hydrolysis products of a lipid as required by the claimed invention as amended.

Further, as Howard expressly teaches hydrolysis products of *defatted* starting material, the Howard reference fails to teach “**polar hydrophilic salts and non-polar unsaponifiables**, wherein said polar hydrophilic salts and said non-polar unsaponifiables comprise the products of hydrolysis of a lipid comprising jojoba oil”, as required by claims **35** and **38** as amended. Thus, the present claims require polar hydrophilic salts to include salts of a lipid, produced by hydrolysis of the lipid in conjunction with unsaponifiables that remain as a result of the hydrolysis of a lipid. Howard fails to teach this.

Indeed, the Examiner cannot cite to Howard for this proposition. Instead the Examiner argues that “the reference disclosed hydrolyzing the jojoba oil by alkali (example 1)” and “since the

reference disclosed hydrolyzed jojoba oil produced by the same method as applicant's method, then the composition produced by the reference will inherently have the same hydrolysis product including salt". The Examiner impermissibly relies on inherent disclosure in this case. The Howard reference does not teach hydrolysis of a lipid comprising jojoba oil to produce polar hydrophilic salts and non-polar unsaponifiabiles. Example 1, as cited by the Examiner, expressly teaches the removal of jojoba oil to yield a defatted jojoba meal for subsequent hydrolysis. The Howard reference does not teach hydrolysis of a lipid, nor a lipid comprising jojoba oil. As the Howard reference teaches hydrolysis of a defatted jojoba meal, polar hydrophilic salts of a lipid are not disclosed in the Howard reference, explicitly or inherently. In fact, the Howard reference fails to teach the use of salts or unsaponifiabiles at all.

In an attempt to further convolute the teachings of Howard, the Examiner states that the "present claims' language does not exclude amino acids, nor aqueous dispersion". This is an impermissible reading of limitations into the claims where none exist in an attempt reconcile irreconcilable differences between the claimed invention and the Howard reference, namely, that the Howard reference fails to teach the polar hydrophilic salts and non-polar unsaponifiabiles that are hydrolysis products of a lipid comprising jojoba oil, as required by claims **35** and **38** as amended.

Further, the Examiner asserts that "the claims' language does not exclude removal of insolubles." The removal of insolubles of jojoba protein after hydrolysis, as taught, for example at col. 4, lines 50-55 of the Howard reference, is inapplicable to the method that includes providing a "composition comprising polar hydrophilic salts and non-polar unsaponifiabiles, wherein said polar hydrophilic salts and said non-polar unsaponifiabiles comprise the products of hydrolysis of a lipid" as required by the claimed invention as amended.

Moreover, to the extent that the Examiner implies as much, it is inaccurate to equate insoluble with unsaponifiabiles. Insoluble is an adjective describing whether a compound dissolves when introduced to a particular solvent, while unsaponifiabiles defines a category of compounds that do not undergo a chemical transformation as a result of hydrolysis. In the Howard reference,

solubility appears to be relative solubility in a 50% NaOH solution. *See* Howard col. 4, lines 15-25. What solvent does the Examiner purport to apply to the claimed invention?

It is important to note that the Examiner is either unwilling or unable to assert how the Howard reference does, or could, teach a “composition [that] comprises polar hydrophilic salts and non-polar unsaponifiables, wherein said polar hydrophilic salts and said non-polar unsaponifiables comprise the products of hydrolysis of a lipid comprising jojoba oil”, as required by claims **35** and **38** as amended.

Next, the Examiner asserts that “[j]ojoba oil inherently has the same amount of unsaponifiable materials prior to hydrolysis”. Applicant is affirmatively unaware as to how this assertion affects the patentability of the claimed invention, which includes use of a “composition comprises polar hydrophilic salts and non-polar unsaponifiables, wherein said polar hydrophilic salts and said non-polar unsaponifiables comprise the products of hydrolysis of a lipid comprising jojoba oil”, and respectfully requests clarification of the same.

The Examiner further argues that “the reference disclosed the same method as applicant’s method of obtaining the claimed composition that comprises hydrophilic salts and non-polar unsaponifiable materials.” The Examiner then concludes that “since the reference disclosed hydrolyzed jojoba oil produced by same method as applicant’s method, then the composition produced by the reference will inherently have the same hydrolysis product.”

As discussed *vide supra* the Howard reference does not teach “hydrolysis products of a lipid comprising jojoba oil” as required by the claimed invention. The Examiner admits that the Howard reference fails to teach the claimed invention inasmuch as the Examiner relies on “inherent” disclosure of the polar hydrophilic salts and non-saponifiables as products of a hydrolysis of a lipid, as required by the claims as amended. Specifically, the Examiner states that “the product of the present invention is produced by the same method of the reference using the same starting material, and inherently the same product is produced.” However, the

Examiner has not brought forth credible evidence that the “same method” and “same starting material” were used to produce the “same product.” This is because they are not.

Accordingly, the Howard reference does not disclose “polar hydrophilic salts and non-polar unsaponifiables, wherein said polar hydrophilic salts comprise the *products of hydrolysis of a lipid comprising jojoba oil*”, as required by claims **35** and **38** as amended of the present invention.

It follows that as the Howard reference fails to disclose the composition in the claimed invention, any properties of this composition cannot be inherently taught in the Howard reference. Specifically, in contrast to the Examiner’s assertion, the Howard reference does not teach a product that “will inherently increase substantivity and neutralize acidic gelling agents because product and their properties are not separable.”

It is inappropriate for the Examiner to rely on inherent disclosure of properties of a composition where the composition is not taught in the prior art. *See* M.P.E.P. § 2112.01 (“products of identical composition cannot have mutually exclusive properties”). Because the Examiner has failed to show how the Howard reference teaches “polar hydrophilic salts and non-polar unsaponifiables, wherein said polar hydrophilic salts and non-polar unsaponifiables comprise the products of hydrolysis of a lipid comprising jojoba oil wherein said lipid comprises at least more than about 10 weight percent long carbon chain material prior to hydrolysis” as required by claims **35** and **38** as amended, the Examiner cannot rely on inherent disclosure of Howard to teach the neutralization of a gelling agent with the composition or the increased substantivity the claimed composition provides.

The Examiner notes, in response to Applicant’s arguments, that “applicant’s attention is directed to the scope of the present claims that are directed to method of providing a composition, and the only step method received by the claims is “adding” material comprising jojoba oil to acid gelling agent.” The Examiner then claims that this step is “disclosed by the reference at col. 2, lines 65-67, as well as the starting elements, as set forth.”

Applicant respectfully submits that this assertion by the Examiner demonstrates the Examiner's failure to appreciate the scope of Applicant's claimed invention as amended. Specifically, the Examiner has failed to appreciate that the hydrolysis products of a lipid comprising jojoba oil are added in an effective amount in order to *neutralize* an acid gelling agent, as required by the claimed invention. In order to further clarify this, claims **35** and **38** have been amended to identify the step of neutralizing the gelling agent with an effective amount of the composition comprising the hydrolysis products of a lipid comprising jojoba oil as discussed *vide supra*.

Even if the Examiner appreciated the scope of the claimed invention, the Examiner would not be able to provide any citation of the Howard reference that teaches neutralization of an acid gelling agent with the composition of the claimed invention. In fact, to the extent that the Howard reference glibly discloses a gelling agent at all, the Howard reference teaches the use of chemicals such as triethanolamine (TEA) or sodium hydroxide (NaOH) to adjust pH of a composition. *See, e.g.*, Howard col. 11, table 8; col. 17, tables 13 and 14.

Moreover, the hydrolysis products of a defatted jojoba meal (*i.e.*, hydrolyzed jojoba protein) in the Howard reference cannot function to neutralize a gelling agent. An acid gelling agent by definition has an acidic pH. In order to neutralize an acidic gelling agent, a compound of basic pH must be added to the acid gelling agent. (*See* Exhibit C, pp. 764). By contrast, the Howard reference teaches increasing acidity of the jojoba protein. For example, the Howard reference teaches that "[i]n step 18, lactic acid was added to the slurry to lower the pH to 4.5...". *See* Howard col. 4, lines 45-46. This pH adjustment step indicates that the hydrolyzed protein preparation has a pH of less than 7.0 and is thus considered an acidic pH. As discussed above, an acid gelling agent must be neutralized using a base. Therefore, the hydrolyzed jojoba protein disclosed in the Howard reference cannot neutralize an acid gelling agent because it has an acidic pH itself and an acid cannot neutralize another acid.

Thus, the Howard reference does not teach neutralization of an acid gelling agent with a composition comprising "polar hydrophilic salts and non-polar unsaponifiables, wherein said

polar hydrophilic salts and non-polar unsaponifiables comprise the products of hydrolysis of a lipid comprising jojoba oil wherein said lipid comprises at least more than about 10 weight percent long carbon chain material prior to hydrolysis”, as required by claims **35** and **38** of the claimed invention.

In addition, the claimed invention requires “a composition for topical application, wherein said composition increases substantivity and neutralizes an acid gelling agent”. As discussed above, the only compounds disclosed in the Howard reference that is capable of neutralizing an acid gelling agent are the harsh chemicals TEA and sodium hydroxide. Neither of these chemicals satisfy the requirement “wherein said composition *increases substantivity*”. To the contrary, TEA is known to be a corrosive and irritating chemical to the eyes and skin and sodium hydroxide is a strong caustic base. (See Exhibit D, Exhibit E p. 4, Exhibit F, Exhibit G p. 4). Even in small amounts that may not be harmful, TEA and sodium hydroxide have no substantive qualities at all.

Accordingly, the Howard reference fails to disclose each and every element of the claimed invention and thus fails to anticipate the claimed invention. As such, Applicant respectfully submits that the §102(e) rejection is improper and should be withdrawn.

CONCLUSION

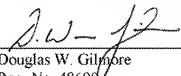
No amendment made herein was related to the statutory requirements of patentability unless expressly stated; rather any amendment not so identified may be considered as directed *inter alia* to clarification of the structure and/or function of the invention and Applicant's best mode for practicing the same. Additionally, no amendment made herein was presented for the purpose of narrowing the scope of any claim, unless Applicant has argued that such amendment was made to distinguish over a particular reference or combination of references. Furthermore, no election to pursue a particular line of argument was made herein at the expense of precluding or otherwise impeding Applicant from raising alternative lines of argument later during prosecution. Applicant's failure to affirmatively assert specific arguments is not intended to be construed as an admission to any particular point raised by the Examiner.

Should the Examiner have any questions regarding this Response and Amendment or feel that a telephone call to the undersigned would be helpful to advance prosecution of this matter, the Examiner is invited to call the undersigned at the number given below.

Respectfully submitted,

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